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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,583

02/08/2007

Sayoko Matsumoto

09812.0126

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04/01/2008

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EXAMINER

GREENE, JAIME M

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

04/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



<b>Office Action Summary</b>	<b>Application No.</b> 10/574,583	<b>Applicant(s)</b> MATSUMOTO ET AL.	
	<b>Examiner</b> JAIME M. GREENE	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/4/06, 2/8/07, 5/30/07, 8/6/07 and 2/12/08</u> .             | 6) <input type="checkbox"/> Other: _____                          |







### **DETAILED ACTION**

1. This action is in response to papers filed 12/5/07. Claims 1-10 are pending and claims 1-4 are under examination on the merits.

#### ***Information Disclosure Statement***

2. The information disclosure statements (IDS) were filed after the mailing date of on 4/4/06, 2/8/07, 5/30/07, 8/6/07 and 2/21/08. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. It should be noted however that references not submitted in English or duplicate references were crossed out as having not been considered.

#### ***Election/Restrictions***

3. Applicant's election of Group I, claims 1-4, in the reply filed on 12/5/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
4. Claims 5-10 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/5/07.

#### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:



The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1 is indefinite over parenthetical recitations of (1) and (2) in lines 4, 5 and 9. Because the recitations are in parentheses it is not clear if these recitations are meant to be a limitation to the claims. Further, it is entirely unclear what this arbitrary identifier means.

8. Claim 1 is vague and indefinite. It is unclear what method/process applicant is intending to encompass and further the claim can comprise a number of alternative embodiments that do not overlap in scope. For example, while the claim recites "by causing an ac electric field", it is unclear whether the limitation "by causing" is part of the preamble or is intended to be an active step.

9. Claims 1 is indefinite over the recitations of "or" in lines 2, 4, and 7. The uses of "or" in this case indicate that the method can be performed in many alternative ways and therefore, the metes and bounds of the claim are unclear.

10. Claims 2-4 depend from claim 1 and are indefinite for the reasons applied to claim 1.

11. Claim 3 recites the limitation "said opposing electrodes" in lines 2-3. When the claim only involves examining the nucleic acid in free form, there is no mention of the use of any electrodes. Therefore, there is insufficient antecedent basis for this limitation in claim 3 for all interpretations of the claim 1.



12. Claim 4 recites the limitation "said stretch" in line 2. Because it is unclear what the active steps are in the method of claim 1 and thereby what the stretch method is, there is therefore insufficient antecedent basis for this limitation in the claim.

13. What about "said stretch"- claim 1 does not recite "a stretch" step- lack of antecedent basis. Explain that the term is in the preamble while claim 4 recites "stretch" as a step.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (Lee, et al. IEEE-NANO 2003, Third IEEE Conference on Nanotechnology, 12-14 Aug. 2003; .2: 729-732).

It is noted that for purposes of this rejection, claim 1 is interpreted as a method of stretching single stranded nucleic acid by applying an AC electric field to the nucleic acid in free form.



Regarding claim 1, Lee teaches separation of single-stranded DNA (ssDNA) in a stretched form in pure water for deposition of the ssDNA onto electrodes (pg 731, col 1). Lee teaches applying AC and DC electric fields to prevent aggregation and stretch the ssDNA (pg 731, col 1). Lee teaches that the frequency of the electric field was 5MHz (i.e. high frequency) (pg 729, col 2).

Regarding claim 3, Lee teaches a pair of aluminum electrodes that have a gap width of 6 $\mu$ m (pg 729, col 2).

Therefore all limitations of these claims have been taught by the reference.

16. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (Lee, et al. IEEE-NANO 2003, Third IEEE Conference on Nanotechnology, 12-14 Aug. 2003; .2: 729-732).

It is noted that for purposes of this rejection, claim 1 is interpreted as a method of causing an AC electric field to action on a single-stranded nucleic acid existing in a form immobilized on one or both of opposing electrodes.

Regarding claim 1, Lee teaches deposition (i.e. immobilization) of ssDNA onto electrodes (pg 731, col 1). Lee teaches applying AC and DC electric fields to prevent aggregation and stretch the ssDNA (pg 731, col 1). Lee teaches that the frequency of the electric field was 5MHz (i.e. high frequency) (pg 729, col 2).

Regarding claim 3, Lee teaches a pair of aluminum electrodes that have a gap width of 6 $\mu$ m (pg 729, col 2).

Therefore all limitations of these claims have been taught by the reference.



Art Unit: 1634

17. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Chou (Chou, et al. Biophys J. 2002 October; 83(4): 2170–2179).

It is noted that for purposes of this rejection, claim 1 is interpreted simply as a method of stretching a single stranded nucleic acid.

Regarding claims 1 and 4, Chou teaches performing electrodeless dielectrophoresis on single-stranded DNA (pg 2175, col 1).

Therefore all limitations of these claims have been taught by the reference.

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over (Lee, et al. IEEE-NANO 2003, Third IEEE Conference on Nanotechnology, 12-14 Aug. 2003; .2: 729-732).

It is noted that this rejection is being applied in view of the interpretations of set forth in sections 15 and 16 above.

Regarding claims 1 and 2, Lee teaches separation of single-stranded DNA (ssDNA) in a stretched form in pure water for deposition of the ssDNA onto electrodes (pg 731, col 1). Lee teaches applying AC and DC electric fields to prevent aggregation and stretch the ssDNA (pg 731, col 1). Lee teaches that the frequency of the AC



Art Unit: 1634

electric field was 5MHz (i.e. high frequency) and the voltage was 0.82V/ $\mu$ m (pg 730, col 1).

While Lee does teach applying an AC electric field with a frequency of 5MHz and a voltage of was 0.82V/ $\mu$ m, Lee does not teach applying a voltage of 1.2V/ $\mu$ m

However, the MPEP teaches "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.).

Therefore, it would have been prima facie obvious to the ordinary artisan and the ordinary artisan would have been motivated to modify the method of Lee by adjusting the voltage as part of standard optimization practices in the art.



There is a reasonable expectation of success because it is common practice in the art to adjust the general conditions of an experiment as a routine means of optimization.

20. Claims 1-2 and 4 are rejected under 35 U.S.C. 103(a) as being obvious over Segawa (Segawa, et al. US PGPub 20060127904, published 6/15/06, filed 8/20/03).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Regarding claim 1, Segawa teaches stretching nucleotide probes by an electric field generated in the vicinity of ends of scanning electrodes (pg 1, para 13). Segawa teaches that the stretched nucleotide probes in the reaction region can migrate toward



Art Unit: 1634

the ends of the scanning electrodes by dielectrophoresis due to the non-uniform electric field and that the nucleotide probes in a stretched form can be immobilized (i.e. in free form or immobilized on electrodes) on the scanning electrodes so as to bridge between the electrodes (pg 1, para 13)). Segawa teaches that the electric fields generated by the counter electrodes of the sensor chip according to the present invention are of alternate current (i.e. AC electric field) (pg 3, para 26). Segawa teaches that the parameters of the electric field between the counter electrodes are about  $1\text{V}/\mu\text{m}$  and about 1 MHz (i.e. high frequency) (pg 4, para 70).

Regarding claim 2, Segawa teaches that the parameters of the electric field between the counter electrodes are about  $1\text{V}/\mu\text{m}$  and about 1 MHz (i.e. high frequency) (pg 4, para 70).

Regarding claim 4, Segawa teaches that the electric field is a non-uniform electric field (i.e. dielectrophoresis) (pg 1, para 13).

Although Segawa teaches stretching nucleotide probes with an electric field of about 1MHz, Segawa does not explicitly teach (claim 1) that the probes are single stranded and (claim 2) that the electric field strength is  $1.2\text{ V}/\mu\text{m}$  or greater.

However, the MPEP teaches "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between  $40^{\circ}\text{C}$  and  $80^{\circ}\text{C}$  and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference



Art Unit: 1634

process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.).

Therefore, it would have been prima facie obvious to the ordinary artisan and the ordinary artisan would have been motivated to modify the method of Lee by adjusting the voltage as part of standard optimization practices in the art.

There is a reasonable expectation of success because it is common practice in the art to adjust the general conditions of an experiment as a routine means of optimization.

Also nucleic acid probes are commonly single stranded in the art and therefore it would have been prima facie obvious to the ordinary artisan at the time the invention was made to use single stranded probes because probes are normally single-stranded in the art.

21. Claims 3 is rejected under 35 U.S.C. 103(a) as being obvious over Segawa (Segawa, et al. US PGPub 20060127904, published 6/15/06, filed 8/20/03), as applied



Art Unit: 1634

to claims 1-2 and 4 above, further in view of Lee (Lee, et al. IEEE-NANO 2003, Third IEEE Conference on Nanotechnology, 12-14 Aug. 2003; .2: 729-732).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Segawa teaches all of the limitations of claim 1 as described above.

Also, while Segawa does teach using opposing electrodes, Segawa also does not teach (claim 3) that the distance between the opposing electrodes is 40µm or shorter.



However, Lee teaches applying an AC electric and stretching ssDNA between two electrodes (pg 731, col 1). Lee teaches that the electrodes are pair of aluminum electrodes that have a gap width of 6 $\mu$ m (pg 729, col 2).

Therefore, it would have been prima facie obvious to the ordinary artisan at the time the invention was made to modify the method of Segawa by using electrodes that are 6 $\mu$ m apart as a means of stretching the nucleic acids.

The ordinary artisan would have been motivated to modify the method of Segawa by using electrodes that are 6 $\mu$ m apart as a means of stretching the nucleic acids.

There is a reasonable expectation of success because both Segawa and Lee teach stretching nucleic acids that are between opposing electrodes.

### ***Double Patenting***

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.



Art Unit: 1634

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 1 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 10535714. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 29 of '714 includes a step of stretching nucleotide probes in an AC electric field by dielectrophoresis. Although claim 29 of '714 does not explicitly identify the probes as single stranded, probes are commonly single stranded in the art and therefore it would have been prima facie obvious to the ordinary artisan to perform the method with single stranded probes. Therefore, claim 29 renders obvious the method of instant claims 1 and 4 of stretching single stranded nucleic acid by dielectrophoresis using an AC electric field.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAIME M. GREENE whose telephone number is (571)270-3052. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, ALT. Friday, EST.



Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jaime M. Greene 2/29/08

/Ram R. Shukla/

Supervisory Patent Examiner, Art Unit 1634